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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,899	06/04/2001	Nnochiri N. Ekwuribe	9233-54	5139

20792 7590 08/13/2003

MYERS BIGEL SIBLEY & SAJOVEC  
PO BOX 37428  
RALEIGH, NC 27627

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

17

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Interview Summary

Application No.

09/873,899

Applicant(s)

EKWURIBE ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1654

All participants (applicant, applicant's representative, PTO personnel):

(1) Jeffrey E. Russel.

(3) \_\_\_\_\_.

(2) Mary L. miller.

(4) \_\_\_\_\_.

Date of Interview: 12 August 2003.

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: All.

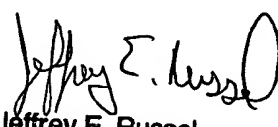
Identification of prior art discussed: Ekwuribe et al '228; Radha Krishnan et al article.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Reviewed drafts of declarations by Ekwuribe and by Radhakrishnan. Executed declarations will be effective to show that the two references are not "by another" and therefore not available as prior art under 35 U.S.C. 102(e) or (a), will overcome rejections set forth in paragraphs 6, 7, and 8 of Office action mailed June 6, 2003.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

  
Jeffrey E. Russel  
Primary Patent Examiner  
Art Unit 1654

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

#### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.

Application Serial No.: 09/873,899

Filed: June 4, 2001

For: *MIXTURES OF INSULIN DRUG-OLIGOMER CONJUGATES COMPRISING  
POLYALKYLENE GLYCOL, USES THEREOF,  
AND METHODS OF MAKING*

**Declaration of Balasingam Radhakrishnan, Ph.D.  
Under 37 C.F.R. § 1.131 and *In re Katz*<sup>1</sup>**

Sir:

I, Balasingam Radhakrishnan, Ph.D. hereby declare as follows:

1. I am the Director of Chemistry Development and Manufacturing at Nobex Corporation located in Research Triangle Park, N.C.
2. I am a named co-inventor on U.S. Patent Application Serial No. 09/873,899 entitled, "Mixtures of Insulin Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making" (*hereinafter*, "the '899 application"), filed June 4, 2001.
3. The subject matter of the application was invented by Nnochiri N. Ekwuribe, Christopher H. Price, Aslam M. Ansari, Amy L. Odenbaugh and myself. Each of us is named as an inventor on the '899 application.
4. Radhakrishnan et al. Stability and Physical Characteristics of Orally Active Amphiphilic Human Insulin Analog, Methoxy (Polyethylene Glycol) Hexanoyl Human Recombinant Insulin (HIM2). The 27th International Symposium on Controlled Release of Bioactive Materials and the Third Consumer and Diversified Products Conference, July 7-13, 2000, was co-authored by one of the Inventors,

<sup>1</sup> 687 F.2d 450, 215 U.S.P.Q. 14 (C.C.P.A. 1982).

Balasingam Radhakrishnan, and two additional authors: J.S. Rajagopalan and J. Burnham.

5. Some of the experiments described in the Radhakrishnan et al. reference were conducted by J.S. Rajagopalan and J. Burnham. These experiments were under the direction and supervision of one or more of the Inventors.
6. Amy L. Odenbaugh is not an author on the Radhakrishnan et al. reference.
7. The authors named on the Radhakrishnan et al. reference who are not included as inventors on the above-captioned patent application did not contribute to the conception of the claimed invention set forth in the above-captioned patent application.
8. For the reasons set forth above, the inventors named on the above-captioned patent application are the true inventors thereof.
9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Balasingam Radhakrishnan, Ph.D.

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Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.

Application Serial No.: 09/873,899

Filed: June 4, 2001

For: *MIXTURES OF INSULIN DRUG-OLIGOMER CONJUGATES COMPRISING  
POLYALKYLENE GLYCOL, USES THEREOF,  
AND METHODS OF MAKING*

**Declaration of Nnochiri N. Ekwuribe  
Under 37 C.F.R. § 1.132**

Sir:

I, Nnochiri N. Ekwuribe, hereby declare as follows:

1. I am a named co-inventor on U.S. Patent Application Serial No. 09/873,899, entitled "Mixtures of Insulin Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making" ("the '899 application"), filed June 4, 2001. The other co-inventors on this application are Christopher H. Price, Aslam M. Ansari and Amy Odenbaugh.
2. I am also a named co-inventor on U.S. Patent Application Serial No. 10/075,097, entitled "Methods of Treating Diabetes Mellitus" (the '097 application"), filed February 13, 2002 and claiming priority under 35 U.S.C. § 119(e) to provisional application serial number 60/269,2001, filed February 15, 2001. The other co-inventors on this application are Christopher H. Price, James Gordon Still and Jennifer Ann Filbey. Additional co-inventors Aslam M. Ansari, Amy L Odenbaugh and Balasingam Radhakrishnan have been added to this application as set forth in a Request to Correct Inventorship Under 37 C.F.R. § 1.48(c), a copy of which is attached hereto.
3. The '097 application was published by the U.S. Patent and Trademark Office as Publication No. US 2003/0050228 A1 on March 13, 2003. This publication is the basis for a rejection under 35 U.S.C. § 102(e) of pending claims 1-3, 7-11, 17, 29, 30,

40, 41, 46-48, 50 and 52 in the '899 application because the '097 application, including claims 170, 183 and 186, allegedly teaches and claims monodispersed mixtures of an insulin drug-oligomer conjugate where the oligomer is  $C(=O)-(CH_2)_5-OC_2H_4)_7-OCH_3$  attached to Lys<sup>B29</sup>. The qualification of the '097 application publication as prior art against the instant claims is stated in the June 6, 2003 Office Action to be on the basis that the disclosure of the monodispersed mixtures is supported by the disclosure of the provisional application upon which it claims priority and because the inventorship of the '097 application is different from the inventorship of the instant application.

4. The subject matter of the '097 application upon which the Examiner is relying in support of the 35 U.S.C. § 102(e) rejection of claims in the '899 application was invented by Nnochiri N. Ekwuribe, Christopher H. Price, Balasingam Radhakrishnan, Aslam Ansari and Amy L. Odenbaugh.
5. The subject matter of claims 1-3, 7-11, 17, 29, 30, 40, 41, 46-48, 50 and 52, which are rejected under 35 U.S.C. § 102(e) in the '899 application was invented by Nnochiri N. Ekwuribe, Christopher H. Price, Balasingam Radhakrishnan, Aslam Ansari and Amy L. Odenbaugh.
6. Thus, the inventors of the subject matter of the '097 application upon which the Examiner is relying and the inventors of the subject matter of the claims rejected under 35 U.S.C. § 102(e) in the '899 application are the same.
7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Attorney Docket No. 9233.54  
Application Serial No.: 09/873,899  
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Nnochiri N. Ekwuribe

\_\_\_\_\_  
Date